

**DEPARTMENT:** Pharmacy

**PROCEDURE:** PS-200

**SUBJECT:** Sterile Products: Aseptic Technique

**PURPOSE:** To ensure proper preparations of all sterile products compounded in FMDH.

**RESPONSIBILITY:** Pharmacy

**POLICY:**

Aseptic technique shall be used to reconstitute and prepare sterile products.

**PROCEDURE:**

1) COMPETENCY AND TRAINING

- a. Competency will be assessed upon hiring and on an annual basis by completing the following requirements:
  - i. Media Fill Test – Medium risk
  - ii. Gloved Fingertip Testing
    1. Must be 0 CFU/cubic meter on initial test
    2. Must be at or less than 3 CFU/cubic meter for subsequent tests
  - iii. Observation of Aseptic technique
  - iv. Passing a Written Competency test

2) ASEPTIC TECHNIQUE

- a. When provided by the pharmacy, medications are to be prepared in the Containment isolator.
- b. Clean the drug preparation area with an approved microbicide agent.
- c. Obtain the basic parenteral solutions, additive drugs, syringes, needles, swabs, etc.
- d. Wash hands prior to handling drugs and as needed during the procedure.
- e. Maintain the integrity of sterile drugs. Remove outer metal lids or protective covers, but do not remove rubber closures or diaphragms.
- f. Do not touch areas that will contact the solution or drugs.
- g. Clean diaphragms, injection ports and ampule necks with 70% alcohol.
- h. Ensure that seals on syringe and needle packages are intact.
- i. Ensure that the syringe is the appropriate size and needle is the appropriate gauge and length.
- j. Ensure that touch contamination does not occur when attaching needles to syringes.
- k. Use a separate syringe and needle for each additive.
- l. Make entries into diaphragms/ports with the bevel of the needle facing up and use a slight downward pressure.
- m. Reconstitute drugs according to manufacturer's instructions and as described below—
- n. Use proper technique and follow the manufacturer's instructions.
- o. Determine the correct amount of diluent to use.
- p. Inject air equal to the amount of diluent to be removed from the vial.
- q. Withdraw the diluent and transfer into the drug vial, venting if necessary.
- r. Mix the drug and diluent according to manufacturer's instructions.
- s. Inspect the final product.